REGULATIONS FOR USE OF RECOMBINANT DNA MOLECULE TECHNOLOGY

The Board of Health, Town of Norwood, Massachusetts acting under the authority of Section 31, Chapter III of the General Laws and amendments and additions thereto, and by any other power thereto enabling, has duly made and adopted the following rules and regulations in the interest of and for the preservation of the public health.

1) APPLICABILITY

All activities associated with constructing and/or propagating: a) recombinant DNA (rDNA) molecules, and b) organisms and viruses containing rDNA molecules within the Town of Norwood shall be performed in strict accordance with these regulations and with NIH Guidelines as defined in Section 2-C below. The regulations shall govern where they differ from the Guidelines. These regulations do not apply to finished products which contain rDNA molecules and which have been approved by other government regulatory agencies for medical or other purposes.

2) DEFINITIONS

For the purpose of these regulations, the following are adopted:

A) Large Scale - The use of more than ten liters but less than 5,000 liters of rDNA culture.

B) Significant Deviation - Any deviation that might have an adverse effect on personal or public health.

C) Guidelines:

(1) The most recent version and any additional approvals of the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register.

(2) In the event that the National Institutes of Health shall discontinue or abolish their guidelines, those guidelines in effect and approved by the Board of Health at the time of such discontinuance shall remain in effect.

3) NORWOOD BIOSAFETY OFFICER

A) The Director of Public Health shall serve as the Norwood Biosafety Officer for the purpose of overseeing all use of rDNA in Norwood and advising the Board of Health.

B) Specific responsibilities of the Norwood Biosafety Officer are as follows:

(1) Establishing policies, procedures and criteria to aid in the implementation of this ordinance.

(2) Reviewing all amendments to the Guidelines before submitting their recommendations to the Board of Health for approval.

(3) Reviewing all applications for permits for the use of rDNA in Norwood for compliance with the Guidelines and conformity with such other regulations as the Board of Health may from time to time promulgate.

(4) Reviewing institutions' manuals, worker training programs, health-safety programs and monitoring procedures.

(5) Determining the manner in which institutions and Institutional Biosafety Committees make reports, applications or recommendations for the Norwood Biosafety Officer and the type of information required. Reviewing such reports, applications and recommendations and approving where appropriate. Carrying out site visits to institutional facilities.

(6) Developing a procedure for members of institutions to report to the Norwood Biosafety Officer violations of these regulations, the Guidelines, or any other health regulations the Board of Health may promulgate.

4) INSTITUTIONAL BIOSAFETY COMMITTEE

(1) The Institutional Biosafety Committee (IBC), established by the Guidelines, shall have as members, in addition to the corporate representatives, one community representative, the Director of Health and a Board of Health member or his/her designee. The community representative shall be appointed by the Board of Health.

(2) The Institutional Biolsafety Committee shall meet on a regular basis. All minutes of the Institutional Biosafety Committee meetings must be forwarded to the Board of Health or the Norwood Biosafety Officer.

(3) The community member of the Institutional Biosafety Committee, the Director of Health and the Board of Health member or his/her designee, shall have no financial interest in the institution or any other institution in competition therewith, and such representatives shall be bound to the same provisions as to non-disclosure and non-use of proprietary information and trade secrets as all other members of Institutional Biosafety Committee, except to the extent necessary to alleviate any public health hazard. As used in this regulation, proprietary information and trade secrets shall be defined as set forth under the laws of the Commonwealth of Massachusetts.

(4) In accordance with the Guidelines, the Institutional Biosafety Committee, acting on behalf of the institution, reviews all rDNA use for compliance with the Guidelines and approves those projects that conform with the Guidelines. A description of each protocol approved by the Institutional Biosafety Committee, including all organisms and the containment to be used, and a statement certifying the experiment conforms with the Guidelines, shall be filed with the Norwood Biosafety Officer or the Board of Health.

(5) All information sent to the Board of Health or the Norwood Biosafety Officer shall have any proprietary information trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the Institutional Biosafety Committee.

5) REGISTRATION

rDNA users in the following categories:

- Users whose experiments are all exempt from NIH Guidelines under Section III-E; (BL-1)
- Users not constructing rDNA organisms propagating them;

are required to register proposed work with Norwood Biosafety Officer. Written registration is required prior to commencement of work and includes:

1. Name and c.v. of a person in the organization familiar with the proposed rDNA work and the NIH Guidelines.

2. A brief summary from the above-named person describing the proposed work and giving:
   a. Name and type of organisms (host/donor [foreign DNA]/vector) being used.
   b. Reference to the section of the NIH Guidelines where the work falls.
   c. If recombinant molecules containing eucaryotic viruses are propagated in cells, give the approximate percentage of viral genome present.
   d. The scale (in liters) on which the organisms will be grown.
   e. An assurance that all work will be carried out following the NIH Guidelines where applicable, at appropriate BL level and that exempt work will be done at BL1.
   f. Name of biological waste handler (if any) and written assurance that all waste will be disposed of according to all applicable federal, state and local codes.

3. An annual report summarizing the work performed over the past year and addressing any ongoing work according to the format given in 2 above.

4. A registration fee of $100.00, due upon initial application and upon annual renewals.

Upon receiving and reviewing the submitted information, the Norwood Biosafety Officer may require additional information to be submitted, and it may recommend to the Board of Health other procedures or safeguards as it deems appropriate up to and including full permit application under the existing regulation.

6) PERMITS

A) All institutions planning to use rDNA in accordance with NIH Guidelines for BL-2 must obtain a permit from the Board of Health with the prior approval of the Norwood Biosafety Officer before commencing said technology. All permits are issued for one year and may be revoked for cause.

B) Institutions seeking such a permit from the Board of Health must first submit the following to the Norwood Biosafety Officer.

   (1) A plot plan showing the proposed location of the facility and a floor plan showing the internal layout of the facility.

(2) A list or all organisms, containment levels, and decontamination procedures to be employed.

(3) A plan for a screening process to insure the purity of the strain of host organisms used in the experiments and to test organisms resulting from such experiments for their resistance to commonly used therapeutic antibiotics. Host organisms obtained from independent laboratories shall undergo the same screening process.

(4) A plan for systematic monitoring of waste to assure that surviving rDNA organisms will not be released into the environment.

(5) A plan for systematic pest control management in laboratories, contiguous facilities and food service establishments in the same building. All waste disposal will be done in accordance with 105 CMR 480.000, Chapter VIII, Sanitary Code, Storage and Disposal of Infectious or Physically Dangerous or Biological Waste.

(6) A plan for systematic security of the premises.

(7) The institution's health monitoring, health surveillance and safety manuals, together with the plan for an appropriate medical surveillance program as determined by the Institutional Biosafety Committee for all persons engaged in the use of rDNA. Such programs shall include, but shall not necessarily be limited to:

a) Prompt reporting to the Institutional Biosafety Committee of employee illnesses that are potentially related to rDNA use.

b) Retention of medical and health records for at least ten years.

c) Medical or employee health records shall be made available for inspection and may be used for public health studies.

d) A training program of safeguards and safety procedures for personnel.

(8) The name(s) of the Principal Investigator(s) responsible for enforcing Policies of the Institutional Biosafety Committee.

(9) A plan for orienting representatives of the Norwood Health, Fire and Police Departments to the physical plant and to procedures to be utilized in the event of an emergency.

(10) Written agreement to allow inspection of facilities and pertinent records by the Norwood Biosafety Officer.

C) The Norwood Biosafety Officer shall review the institution's application for a permit and supporting documents and make its recommendation of the same within 30 days to the Board of Health. The Board of Health shall take final action on the permit application within 60 days after the application is filed. The period within which final action shall be

taken may be extended for a definite period by mutual consent of the Board of Health and the applicant.

D) An application fee of $1,000 for the original application shall be assessed for the expenses incurred for salary, staff, inspection, reviews and professional assistance related to the work involved in determining compliance with these regulations. This shall be a one-time fee.

E) The fee for a permit granted by the Board of Health, for annual renewal thereof, shall be $500.00.

F) All facilities in existence prior to this regulation shall be required to apply for a permit and comply with the requirements within 365 days.

7) INSPECTION AND REVIEW

A) All institutions involved in the use of rDNA shall allow inspection of their facilities, procedures and practices in order to confirm compliance with this ordinance.

B) The Board of Health shall retain a professionally competent person, agency or institution to perform inspections and reviews. The results shall be reported to the Board of Health, the Norwood Biosafety Officer and the institution involved.

C) The Board of Health, its employees, and any individual or institution employed to perform inspections shall maintain the confidentiality of all proprietary information released to them by reason of this regulation.

8) RESTRICTIONS

A) rDNA use classified by the Guidelines as requiring any BL3 physical containment measures shall be permitted by variance only as described in Section 11.

B) rDNA use classified by the guidelines as requiring any BL4 physical containment measures as prescribed by Appendix G of the Guidelines under Standard Microbiological Practices, Special Practice Containment Practices, Containment Equipment or Laboratory Facilities shall not be permitted.

C) Experiments, for which containment levels are not prescribed in the Guidelines, shall be approved by the Norwood Biosafety Officer before the experiment is initiated.

D) Use of more than 5,000 liters of rDNA culture shall not be permitted.

E) There shall be no deliberate release into the environment, that is to sewers, drains, or the air, of any organisms containing rDNA.

F) The institution shall report within 24 hours to the Norwood Board of Health, followed by a written report within 15 days, any significant accidents or illnesses or releases related to the use of rDNA. An additional inspection of facilities and procedures may be deemed necessary by the Norwood Biosafety Officer based upon its judgement of the nature and extent of the problem.

9) PENALTIES

A) Violation of the conditions of these regulations shall subject the violator to a fine of five hundred ($500.00) per day and in addition the facility in which the violation occurs may be closed by the Board of Health. Each day of violation shall constitute a separate and distinct offense.

B) Once a permit has been issued or a registration filed, it may be revoked by the Board of Health upon determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations, the permit agreements or the guidelines or, if in the opinion of the Board of Health, the rDNA use causes a nuisance, or adversely affects the public health, safety and welfare in Norwood.

10) SEPARABILITY

Each part of these regulations is construed as separate to the end, in that if any section, item, sentence, clause or phrase is held invalid for any reason, the remainder of these regulations shall continue in full force and effect.

11) VARIANCE

The Board of Health may vary the application of any provision of these regulations with respect to any particular case when, in its opinion, the enforcement thereof would do manifest injustice, provided that the decision of the Board of Health is not in conflict with the spirit of these standards. Any variance granted by the Board of Health must be in writing with a copy available to the public at all responsible hours in the Office of the Town Clerk and in the Office of the Board of Health.

Norwood Board of Health

Alice W. Marks, Chairman
Frances J. Harwood
Joan M. Jacobs

Effective Date: October 1, 2001